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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ALLERGAN SALES, LLC and ALLERGAN, INC.	§	
Plaintiffs,	§	
v.	§	Civil Action No. 2-17-CV-10129
SANDOZ, INC. and ALCON LABORATORIES, INC.	§	Judge William H. Walls Mag. Judge Cathy L. Waldor
Defendants,	§	

DEFENDANTS' ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendants Sandoz, Inc. ("Sandoz") and Alcon Laboratories, Inc. ("Alcon") hereby submit their Original Answer, Defenses, and Counterclaims to the Complaint filed by Plaintiffs Allergan Sales, LLC and Allergan, Inc. (collectively, "Allergan").

ANSWER TO PLAINTIFFS' COMPLAINT

Pursuant to Fed. R. Civ. P. 8(b)(3), Defendants deny all allegations in Allergan's Complaint except those specifically admitted below. More specifically, Defendants deny that they infringe any valid, enforceable, and properly construed claims of United States Patent No.

9,770,453 (the "'453 patent"), deny that there is any basis for this suit, deny that Plaintiffs are entitled to any relief, and deny all allegations not specifically admitted in this answer.

Defendants additionally submit their Defenses and Counterclaims against Plaintiffs. In particular, Defendants seek a judgment denying and dismissing with prejudice Plaintiffs' claims against Defendants and declaring the '453 patent invalid and not infringed. Defendants further seek an order finding that this is an exceptional case under 35 U.S.C. § 285, and awarding Defendants their attorneys' fees, expenses, and costs in defending this action.

The Nature of the Action

COMPLAINT PARA. 1:

This is an action for infringement of United States Patent No. 9,770,453 (the "'453 patent") under 35 U.S.C. § 271(e)(2) and for Declaratory Judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(b) and (c) relating to Allergan's commercially successful product, Combigan®.

1. Defendants admit that the Complaint purports to allege an action for infringement under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*, and for Declaratory Judgment under 28 U.S.C. §§ 2201–02. Defendants deny that they have committed any acts of patent infringement. Defendants deny any remaining allegations set forth in this paragraph.

The Parties

COMPLAINT PARA. 2:

Allergan Sales, LLC is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 5 Giralda Farms, Madison, New Jersey, 07940.

2. Defendants lack information or knowledge sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, deny them.

COMPLAINT PARA. 3:

Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 5 Giralda Farms, Madison, New Jersey, 07940.

3. Defendants lack information or knowledge sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, deny them.

COMPLAINT PARA. 4:

On information and belief, defendant Sandoz, Inc. is a Colorado corporation and a division of Novartis Corporation. Novartis Corporation is located at One Health Plaza, East Hanover, NJ 07936, and Sandoz's principal place of business at 100 College Road West, Princeton, New Jersey 08540.

4. Sandoz admits that it is a Colorado corporation and that it has a principal place of business at 100 College Road West, Princeton, New Jersey 08540. Sandoz further admits that Novartis Corporation is located at One Health Plaza, East Hanover, NJ 07936 and that Novartis AG is Sandoz' ultimate corporate parent. Other statements in this paragraph are conclusions of law to which no answer is required. Sandoz otherwise denies the remaining allegations in this paragraph. Alcon lacks information or knowledge sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies them.

COMPLAINT PARA. 5:

On information and belief, defendant Alcon Laboratories, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 6201 South Freeway, Fort Worth, TX 76134-2099, and a registered agent at 211 E. 7th Street, Suite 620, Austin, TX 78701-3218.

5. Alcon admits the allegations in this paragraph. Sandoz lacks information or knowledge sufficient to form a belief as to the truth of the allegations in this paragraph and, therefore, denies them.

COMPLAINT PARA. 6:

On information and believe, Sandoz and Alcon are related corporate entities with respect to generic pharmaceuticals. On further information and belief, Sandoz and Alcon each originally filed separate abbreviated new drug applications ("ANDAs") seeking to manufacture generic copies of Allergan's Combigan®. On further information and belief, in approximately 2011, Sandoz and Alcon merged their ANDAs into ANDA No. 91-087, and are working in concert to achieve final approval of their merged ANDA.

6. Defendants admit that they each originally filed separate abbreviated new drug applications ("ANDAs") seeking to manufacture generic copies of Allergan's Combigan® product. Defendants admit that, in approximately 2011, their respective ANDAs merged into ANDA No. 91-087. Other statements in this paragraph are conclusions of law to which no answer is required. Defendants otherwise deny the remaining allegations in this paragraph.

COMPLAINT PARA. 7:

On information and belief, Defendants are in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial jurisdiction.

7. Sandoz admits that it develops, manufactures, and sells quality pharmaceutical products. Alcon admits that it distributes and sells quality pharmaceutical products. Defendants otherwise deny the remaining allegations in this paragraph.

Jurisdiction and Venue

COMPLAINT PARA. 8:

This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq* and the Declaratory Judgment Act. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§1331, 1338, 2201, and 2202.

8. Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to allege an action for infringement under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq*, and for Declaratory Judgment under 28 U.S.C. §§ 2201–02. Defendants admit that this Court may

exercise subject matter jurisdiction over parts of this Complaint under 28 U.S.C. §§ 1331, 1338, 2201, and 2202. Defendants deny that they have committed any acts of patent infringement. Defendants deny any remaining allegations set forth in this paragraph.

COMPLAINT PARA. 9:

This Court has personal jurisdiction over Sandoz by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein. Upon information and belief, Sandoz has a place of business at 100 College Road West, Princeton, NJ 08540, and is registered to do business in New Jersey. Upon information and belief, Sandoz regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. Upon information and belief, Sandoz derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Allergan has been injured in New Jersey because of Defendants' ANDA filing and the causes of action Allergan raises here, as alleged herein.

9. Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz does not contest this Court's personal jurisdiction over Sandoz solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 10:

This Court has personal jurisdiction over Alcon by virtue of its systematic and continuous contacts with this jurisdiction, as alleged herein. Upon information and belief, Alcon's parent corporation, Novartis, has a place of business at One Health Plaza, East Hanover, NJ, 07936. Alcon is registered to do business in New Jersey. Upon information and belief, Alcon regularly and continuously transacts business within New Jersey, including by selling pharmaceutical products in New Jersey. Upon information and belief, Alcon derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey. Allergan has been injured in New Jersey because of Defendants' ANDA filing and the causes of action Allergan raises here, as alleged herein.

10. Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Alcon does not contest this Court's personal jurisdiction over Alcon

solely for the limited purposes of this action only, and reserves the right to contest personal jurisdiction in any other case. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 11:

Venue is proper in this Court under 28 U.S.C. § 1400(b).

11. Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue for the limited purposes of this action only. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 12:

Venue is proper in this District under 28 U.S.C. § 1400(b) because Sandoz "committed an act of infringement' [sic] in this district and has a "regular and established place of business" in this district. Sandoz submitted its ANDA No. 91-087 pursuant to 505(j)(2)(B)(ii) of the FDCA, and, upon receiving approval of its ANDA, will manufacture, sell, offer to sell, and/or import Defendants' proposed generic brimonidine/timolol ophthalmic solution in the United States, including in this district. Thus, Sandoz has committed an act of infringement in this district. Sandoz also has a "regular and established place of business" in this district. Sandoz has a principal place of business at 100 College Road West, Princeton, NJ 08540. Sandoz is also licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration Number 5003732).

12. Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue for the limited purposes of this action only. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 13:

Venue is proper in this District under 28 U.S.C. § 1400(b) because Alcon "committed an act of infringement' [sic] in this district and has a "regular and established place of business" in this district. Alcon, in conjunction with Sandoz, submitted its ANDA No. 91-087 pursuant to 505(j)(2)(B)(ii) of the FDCA, and, upon receiving approval of its ANDA, will manufacture, sell, offer to sell, and/or import Defendants' proposed generic brimonidine/timolol ophthalmic solution in the United States, including in this district. Thus, Alcon has committed an act of infringement in this district. Alcon also has a "regular and established place of business" in this district. Alcon's parent corporation, Novartis, has a principal place of business at One Health Plaza, East HAnover, NJ 07936. Sandoz is also licensed to do business with the New Jersey

Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration Number 5004265).

13. Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue for the limited purposes of this action only. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 14:

The parties have previously litigated cases regarding Defendants' ANDA No. 91-087 and related patents covering Allergan's Combigan® in the Eastern District of Texas. After the Federal Circuit's decision in *In re Cray*, 2017 WL 4201535 (Fed. Cir. Sept. 21, 2017), venue may not lie in that jurisdiction, and Sandoz and Alcon have challenged personal jurisdiction in the Eastern District of Texas in another case pending in that District. As a result, Allergan has filed this action in the District of New Jersey, where Defendant Sandoz has a place of business.

14. Defendants admit that the parties have previously litigated cases regarding Defendants' ANDA No. 91-087 and patents related to the '453 patent in the Eastern District of Texas. Defendants further admit that venue for this action does not lie in the Eastern District of Texas and Plaintiffs have filed this action in the District of New Jersey. Sandoz admits that it has a place of business in New Jersey. Defendants deny that any patents related to the '453 patent cover Allergan's Combigan® product. Defendants deny the remaining allegations of this paragraph.

Background

COMPLAINT PARA. 15:

The '453 patent, entitled "Combination of Brimonidine and Timolol for Topical Ophthalmic Use," issued to Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh on September 26, 2017. A copy of the '453 patent is attached to this complaint as Exhibit A.

15. Defendants admit that the '453 patent bears the title "Combination of Brimonidine and Timolol for Topical Ophthalmic Use," lists on its face Chin-Ming Chang, Gary J. Beck, Cynthia C. Pratt, and Amy L. Batoosingh as inventors, and purports to have issued on

September 26, 2017. Defendants further admit that what purports to be a copy of the '453 patent is attached to the Complaint as Exhibit A. Defendants deny that the '453 patent was duly and legally issued as well as any suggestion that the '453 patent is valid and enforceable. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 16:

Allergan, as assignee, owns the entire right, title, and interest in the '453 patent.

16. Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '453 patent lists on its face "Allergan Sales, LLC" as assignee. Defendants lack information or knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, therefore, deny them.

COMPLAINT PARA. 17:

Allergan is the holder of an approved New Drug Application ("NDA") No. 21-398 for brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, sold under the Combigan® trademark.

17. Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that NDA No. 21-398 for brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%, sold as Allergan's Combigan® product, states on its face that Allergan, Inc. is its holder. Defendants lack information or knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, therefore, deny them.

COMPLAINT PARA. 18:

In conjunction with that NDA, Allergan has listed with the United States Food and Drug Administration ("FDA") eight patents that cover the approved formulation or methods of using the approved formulation of Combigan®. The listed patents are U.S. Patent Nos. 7,030,149, 7,320,976, 7,642,258, 8,133,890, 8,354,409, 8,748,425 9,474,751, and 9,770,453 (collectively,

"the Listed Patents"). The FDA has published these eight patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

18. Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the electronic version of the FDA publication, Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book"), lists U.S. Pat. Nos. 7,030,149, 7,320,976, 7,642,258, 8,133,890, 8,354,409, 8,748,425 9,474,751, and 9,770,453 (collectively, the "Listed Patents") in connection with Allergan's Combigan® product. Defendants deny that any claims of the Listed Patents cover Allergan's Combigan® product. Defendants lack information or knowledge sufficient to form a belief as to the truth of the remaining allegations in this paragraph and, therefore, deny them.

COMPLAINT PARA. 19:

Combigan®, or approved methods of using Combigan®, are covered by at least one claim of the patents listed in the Orange book, including the '453 patent.

19. Denied.

COMPLAINT PARA. 20:

On November 20, 2008, Sandoz submitted its ANDA No. 91-087 to the FDA, seeking approval to commercially manufacture, use, offer for sale, or sell a generic version of Allergan's Combigan® product. Allergan filed suit against Sandoz in the Eastern District of Texas on April 7, 2009. (C.A. No. 2:09-cv-097). Sandoz's ANDA No. 91-087 received tentative approval from the FDA on May 11, 2011.

20. Admitted.

COMPLAINT PARA. 21:

In an August 22, 2011 opinion, the United States District Court for the Eastern District of Texas found that Defendants' proposed generic versions of Combigan® infringed U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258, and that those patents were not invalid. Allergan v. Sandoz, 818 F. Supp. 2d 974 (E.D. Tex. 2011). The Court entered an injunction order on August 25, 2011, stating that Defendants were enjoined from manufacturing their proposed

generic versions of Combigan® until the latest of the expiration dates of U.S. Patent Nos. 7,030,149, 7,320,976, 7,323,463, and 7,642,258.

21. Defendants admit that on August 22, 2011 the District Court for the Eastern District of Texas found that the drug product described in ANDA No. 91-087 infringed claim 4 of U.S. Patent No. 7,030,149, claim 1 of U.S. Pat. No. 7,320,976, claims 1-6 of U.S. Pat. No. 7,323,463, and claims 1-9 of U.S. Pat. No. 7,642,258. Defendants further admit that, on that basis, the Court entered an injunction order on August 25, 2011. Dkt. 262. Defendants further state that claims 1-6 of U.S. Pat. No. 7,323,463 were found invalid by the Federal Circuit. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 22:

On appeal, in a May 1, 2013 opinion, the Federal Circuit held that claim 4 of the '149 patent is not invalid, declined to rule on the validity of the '976 and '258 patents, and ruled that the claims of the '463 patent are invalid. In addition, the opinion affirmed the factual findings of this Court's August 22, 2011 opinion. Defendants did not challenge the district court's findings or conclusions on infringement on appeal. Thereafter, Defendants filed a petition for rehearing and rehearing en banc, which was denied on September 9, 2013, and a petition for a writ of certiorari to the Supreme Court, which was denied on March 31, 2014.

22. Defendants admit that the Federal Circuit issued an opinion on May 1, 2013, wherein the Federal Circuit held that "the claims of the '463 patent are invalid as obvious" and declined to rule on the validity of the '976 and '258 patents. *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1293-94 (Fed. Cir. 2013). Defendants admit that the appeal did not concern infringement. Defendants further admit that the Federal Circuit denied the petition for rehearing on September 9, 2013, and that the Supreme Court denied certiorari on March 31, 2014. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 23:

After the Federal Circuit denied Defendants' rehearing petitions, Defendants filed a motion for relief from Eastern District of Texas Court's judgment under Federal Rule of Civil

Procedure 60 on September 17, 2013. The Court denied that motion on December 3, 2013, and the Federal Circuit affirmed the judgment denial without opinion. (Case No. 2:09-cv-97, D.I. 308; Case No. 2:09-cv-97, D.I. 316.)

23. Defendants admit that Defendants filed a motion on September 17, 2013 in the Eastern District of Texas that was denied on December 3, 2013. Defendants further admit that the Federal Circuit affirmed the decision without an opinion. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 24:

On or about January 26, 2015, Allergan received a letter dated January 23, 2015, signed on behalf of Sandoz by Jean Domenico. The letter stated in part that "Sandoz has now amended its ANDA to include an additional certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) to U.S. Patent No. 8,748,425." The letter alleges that "the claims of the '425 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz Product."

24. Defendants admit that Sandoz sent a letter dated January 23, 2015, signed by Jean Domenico. Defendants further admit that the letter stated that "Sandoz has now amended its ANDA to include an additional certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to U.S. Patent No. 8,748,425." Defendants further admit that the letter correctly stated, "the claims of the '425 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of the Sandoz Product." Defendants lack information or knowledge sufficient to form a belief as to the truth of the date Allergan received the letter and therefore deny it.

COMPLAINT PARA. 25:

Included in the January 23, 2015 letter was an alleged "Detailed Statement" of the factual and legal basis for Sandoz's opinion that the claims of the '149 patent, '258 patent, '976 patent, and '425 patent are invalid and/or will not be infringed by the manufacture, use or sale of Defendants' Product.

25. Admitted.

COMPLAINT PARA. 26:

Allergan filed suit in the Eastern District of Texas on March 9, 2015. (Case No. 2:15-cv-00347, Dkt. 1.) In a December 30, 2016 opinion, the Eastern District of Texas Court found the '149, '976, and '425 patents are not invalid, that the '149 and '976 patents are not infringed, and that the '425 patent is infringed by Defendants' ANDA No. 91-087. The Court therefore ordered that the effective date of any approval of Defendants' ANDA not occur before the expiration of U.S. Patent No. 8,748,425—i.e., April 19, 2022. The Court also ordered that the injunction previously issued, remains in full force and is in no manner limited or disturbed by this judgment.

26. Defendants admit that Allergan filed Case No. 2:15-cv-00347 in the Eastern District of Texas on March 9, 2015. Defendants further admit that on December 30, 2016, the District Court for the Eastern District of Texas found that the drug product described in ANDA No. 91-087 does not infringe claim 4 of the '149 patent or claim 1 of the '976 patent and infringes claims 1-8 of the '425 patent. Dkt. 51. Defendants further admit that, on that basis, the Court ordered that "[t]he injunction issued as part of the Court's judgment in *Allergan I* remains in full force and effect." *Id.* at 23. Defendants deny the remaining allegations of this paragraph.

COMPLAINT PARA. 27:

Defendants appealed the Eastern District of Texas Court's judgment to the Federal Circuit. The Federal Circuit heard oral argument in the case on October 2, 2017, and the case remains pending.

27. Admitted.

COMPLAINT PARA. 28:

Defendants' primary non-infringement argument on appeal, as it had been before the district court in the Eastern District of Texas, is that their proposed product, referred to as Brimonidine Tartrate/Timolol Maleate Ophthalmic Solution (0.2%/0.5%), does not contain 0.5% timolol free base, despite of the name of the product on the label and the references to 0.5% timolol base throughout their ANDA. The claims of the '425 patent recite a method of treatment using a composition comprising 0.2% brimonidine tartrate and 0.5% timolol free base. Defendants acknowledge that their product is made using 0.2% brimonidine tartrate and 0.68% timolol maleate. Defendants further acknowledge that 0.68% timolol maleate contains 0.5% timolol, or 0.5% timolol base.

28. Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the product described in ANDA No. 91-087 does not contain 0.5% timolol free base. Defendants further admit that the claims of the '425 patent contain the phrase "0.2% w/v brimonidine tartrate and 0.5% w/v timolol free base." Defendants further admit that their proposed product is made using 0.2% brimonidine tartrate and 0.68% timolol maleate. Defendants deny the remaining allegations in this paragraph.

COMPLAINT PARA. 29:

On September 26, 2017, the '453 patent issued. Unlike the claims of the prior patents, which generally recited methods of treating glaucoma or ocular hypertension by administering a composition comprising 0.2% w/v brimonidine and 0.5% w/v timolol (or, in the case of the '425 patent, 0.5% w/v timolol free base), the claims of the '453 patent recite a method of treating glaucoma or ocular hypertension by administering a composition comprising 0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate. While Allergan continues to maintain that Defendants infringe the claims requiring 0.2% brimonidine or brimonidine tartrate and 0.5% timolol or timolol free base, Allergan obtained the new claims of the '453 patent specifically to address the district court's claim constructions of "brimonidine" and "timolol," which claim constructions Allergan continues to challenge, and Defendants' non-infringement arguments raised in the case that went to trial in October 2016.

29. Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the '453 patent purportedly issued on September 26, 2017 and that the claims of the '453 patent contain the phrase "0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate." Defendants lack information or knowledge sufficient to form a belief as to the truth of Allergan's assertions regarding its motivations and therefore deny them. Defendants deny the remaining allegations in this paragraph.

COMPLAINT PARA. 30:

The composition of Combigan®, the product covered by the claims, and of Defendants' proposed product under ANDA No. 91-087, is prepared by using 0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate, which those of skill in this field have typically referred to as 0.5% w/v timolol, which is the concentration of timolol free base in 0.68% timolol maleate.

30. Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the product described in ANDA No. 91-087 is prepared using 0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate. Defendants deny the remaining allegations in this paragraph.

COMPLAINT PARA. 31:

In filing their ANDA, Defendants have requested the FDA's approval to market a generic version of Allergan's Combigan® product throughout the United States, including in New Jersey.

31. Sandoz admits that it submitted ANDA No. 91-087 to the FDA, seeking approval to commercially manufacture, use, offer for sale, or sell the drug product described therein in the United States. Defendants deny the remaining allegations in this paragraph.

COMPLAINT PARA. 32:

Defendants' proposed label, like the proposed label for Combigan®, will refer to the product as "brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%," but will also note that the product is a "[s]olution containing 2 mg/mL brimonidine tartrate and 5 mg/mL timolol (6.8 mg/mL timolol maleate)."

32. Sandoz admits that its proposed label will include the phrases "brimonidine tartrate/timolol maleate ophthalmic solution 0.2%/0.5%" and "[s]olution containing 2 mg/mL brimonidine tartrate and 5 mg/mL timolol (6.8 mg/mL timolol maleate)" as outlined in its ANDA No. 91-087. Defendants deny the remaining allegations in this paragraph.

COMPLAINT PARA. 33:

On information and belief, the FDA has tentatively approved ANDA No. 91-087.

33. Admitted.

COMPLAINT PARA. 34:

On information and belief, following FDA approval of ANDA No. 91-087, Defendants will sell the approved generic version of Allergan's Combigan® product throughout the United States, including in New Jersey.

34. Sandoz admits that it submitted ANDA No. 91-087 to the FDA, seeking approval to commercially manufacture, use, offer for sale, or sell the drug product described therein in the United States. Defendants deny the remaining allegations in this paragraph.

Count I

(Infringement of the '453 Patent Under 35 U.S.C. § 271(e)(2) by Sandoz's proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution)

COMPLAINT PARA. 35:

Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

35. Defendants incorporate herein their responses to each of the paragraphs above.

COMPLAINT PARA. 36:

Defendants submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of their proposed Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution throughout the United States. By submitting this application, Defendants have committed an act of infringement of the '453 patent under 35 U.S.C. § 271(e)(2)(A).

36. Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it submitted ANDA No. 91-087 to the FDA under section 505(j) of the FDCA, seeking approval to commercially manufacture, use, offer for sale, or sell the drug product described therein in the United States. Defendants deny the remaining allegations in this paragraph.

COMPLAINT PARA. 37:

The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will constitute an act of infringement of the '453 patent.

37. Denied.

COMPLAINT PARA. 38:

On information and belief, Defendants became aware of the '453 patent no later than the date on which that patent was listed in the Orange Book.

38. Admitted.

COMPLAINT PARA. 39:

On information and belief, Defendants know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will actively induce and contribute to the actual infringement of the '453 patent.

39. Denied.

COMPLAINT PARA. 40:

On information and belief, Defendants know or should know that their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will be especially made for or especially adapted for use in infringement of the '453 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that their commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will actively contribute to the actual infringement of the '453 patent.

40. Denied.

COMPLAINT PARA. 41:

The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution in violation of Allergan's patent rights will cause harm to Allergan for which damages are inadequate.

41. Denied.

Count II

(Declaratory Judgment of Infringement of the '453 Patent Under 35 U.S.C. § 271(b) and (c) by Sandoz's Proposed Generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution)

COMPLAINT PARA. 42:

Allergan incorporates each of the preceding paragraphs as if fully set forth herein.

42. Defendants incorporate herein their responses to each of the paragraphs above.

COMPLAINT PARA. 43:

These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

43. Denied.

COMPLAINT PARA. 44:

There is an actual case or controversy such that the Court may entertain Allergan's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

44. Denied.

COMPLAINT PARA. 45:

Defendants have actual knowledge of the '453 patent

45. Admitted.

COMPLAINT PARA. 46:

On information and belief, Defendants became aware of the '453 patent no later than the date on which that patent was listed in the Orange Book.

46. Admitted.

COMPLAINT PARA. 47:

On information and belief, Defendants have acted with full knowledge of the '453 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '453 patent.

47. Denied.

COMPLAINT PARA. 48:

The commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will induce the actual infringement of the '453 patent.

48. Denied.

COMPLAINT PARA. 49:

On information and belief, Defendants know or should know that their commercial manufacture, use, sale, offer for sale, and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will actively induce the actual infringement of the '453 patent.

49. Denied.

COMPLAINT PARA. 50:

On information and belief, Defendants will encourage another's infringement of the '453 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, which is covered by the claims of the '453 patent.

50. Denied.

COMPLAINT PARA. 51:

Defendants' acts of infringement will be done with knowledge of the '453 patent and with the intent to encourage infringement.

51. Denied.

COMPLAINT PARA. 52:

The foregoing actions by Defendants will constitute active inducement of infringement of the '453 patent.

52. Denied.

COMPLAINT PARA. 53:

On information and belief, Defendants know or should know that their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will be especially made or especially adapted for use in an infringement of the ’453 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

53. Denied.

COMPLAINT PARA. 54:

The commercial manufacture, use, sale, offer for sale, and/or importation of Defendants’ proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will contribute to the actual infringement of the ’453 patent.

54. Denied.

COMPLAINT PARA. 55:

On information and belief, Defendants know or should know that their offer for sale, sale and/or importation of their proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution will contribute to the actual infringement of the ’453 patent.

55. Denied.

COMPLAINT PARA. 56:

The foregoing actions by Defendants will constitute contributory infringement of the ’453 patent.

56. Denied.

COMPLAINT PARA. 57:

On information and belief, Defendants intend to, and will, actively induce and contribute to the infringement of the ’453 patent when ANDA No. 91-087 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

57. Denied.

COMPLAINT PARA. 58:

Allergan is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ proposed generic Brimonidine Tartrate and

Timolol Maleate Ophthalmic Solution by Defendants will induce and/or contribute to infringement of the '453 patent.

58. Denied.

COMPLAINT PARA. 59:

The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, which will actively induce and/or contribute to infringement of the '453 patent, in violation of Allergan's patent rights, will cause harm to Allergan for which damages are inadequate.

59. Denied.

COMPLAINT PARA. 60:

Unless Defendants are enjoined from actively inducing and contributing to the infringement of the '453 patent, Allergan will suffer irreparable injury for which damages are an inadequate remedy.

60. Denied.

COMPLAINT PARA. 61:

On information and belief, despite having actual notice of the '453 patent, Defendants continue to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the '453 patent in disregard of Allergan's rights, making this case exceptional and entitling Allergan to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

61. Denied.

Answer to Plaintiffs' Prayer

All remaining allegations not specifically admitted herein are denied. This paragraph and subparagraphs "a" through "j" constitute a prayer for relief. Defendants deny that Plaintiffs are entitled to judgment or to any relief, legal or equitable, and specifically deny that Plaintiffs are entitled to each item of relief requested in each of subparagraphs "a" through "j."

Jury Demand

Sandoz demands trial by jury as to all issues so triable.

General Denial

Except as expressly admitted herein, Defendants deny each allegation contained in the Complaint.

Further responding to the Complaint, Defendants allege as follows:

DEFENSES

Defendants allege and assert the following defenses in response to the allegations in Plaintiffs' Complaint, undertaking the burden of proof only as to those defenses deemed affirmative defenses by law.

First Defense
(Non-infringement)

1. Defendants have not infringed and do not infringe any valid and enforceable claim of the '453 patent.

2. Defendants incorporate by reference the allegations set forth in their COUNTERCLAIMS below as if fully set forth herein.

Second Defense
(Invalidity)

3. One or more claims of the '453 patent are invalid for failure to satisfy one or more provisions of the patentability requirements specified in 35 U.S.C. §101 *et seq.*, including without limitation, §§ 101, 102, 103, and 112.

4. Defendants incorporate by reference the allegations set forth in their COUNTERCLAIMS below as if fully set forth herein.

Third Defense
(No Entitlement to Injunctive Relief)

5. Plaintiffs are not entitled to injunctive relief against Defendants because any alleged injury to Plaintiffs as a result of Defendants' alleged activities is not immediate or irreparable, and Plaintiffs have an adequate remedy at law. Furthermore, the balance of hardships favors Defendants, and an injunction against Defendants would harm the public interest.

Fourth Defense
(Statutory Limitations on Damages and Costs)

6. Plaintiffs' claims for damages and costs are limited by 35 U.S.C. §§ 286, 287, and/or 288.

Fifth Defense
(Prosecution Laches)

7. Plaintiffs' claim for infringement is barred by the doctrine of prosecution laches.

Sixth Defense
(Failure to State a Claim)

8. Plaintiffs have failed to state a claim upon which relief can be granted.

Seventh Defense
(Lack of Subject Matter Jurisdiction)

9. This Court lacks subject matter jurisdiction over any and all claims asserted under 25 U.S.C. § 271(a), (b), and (c).

Eighth Defense
(Not an Exceptional Case)

10. Defendants' actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

Other Defenses

11. Defendants' investigation is ongoing and Defendants have not yet obtained discovery from Plaintiffs, the prosecuting attorney, or third parties. Defendants reserve the right

to amend their Answer to include other defenses that Defendants may learn of during the course of their investigation and after obtaining discovery from Plaintiffs, the prosecuting attorney, and third parties.

COUNTERCLAIMS AGAINST PLAINTIFFS

Defendants assert the following Counterclaims against Plaintiffs, demand a jury trial, and allege as follows:

1. Defendants repeat and incorporate by reference each of the foregoing paragraphs of Defendants' Answer to Plaintiffs' Complaint.

The Nature of the Action

2. Plaintiffs market and sell Allergan's Combigan® product, an ophthalmic combination of 0.2% brimonidine tartrate and 0.68% timolol maleate for the treatment of glaucoma or ocular hypertension. This case stems from the submission of an Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") for approval to market a generic version of Allergan's Combigan® product for treatment of ocular hypertension. Defendants already obtained a judgment of invalidity of U.S. Pat. No. 7,323,463 ("the '463 patent") on May 1, 2013. Defendants further obtained a judgment of non-infringement of U.S. Pat. Nos. 7,030,149 ("the '149 patent") and 7,320,976 ("the '976 patent") on December 30, 2016. Through these counterclaims, Defendants seek declaratory judgments of non-infringement and invalidity regarding U.S. Pat. No. 9,770,453 (the "'453 patent"), with the objective of allowing competition for Plaintiff's Combigan® product.

3. Plaintiffs allege that they are the assignee of the '453 patent and that Defendants infringe the '453 patent. Defendants deny that they infringe any valid, enforceable, and properly construed claim of the '453 patent. There is an actual justiciable controversy between Defendants and Plaintiffs concerning the non-infringement of the '453 patent.

The Parties

4. Counterclaim Plaintiff Sandoz Inc. is a Colorado corporation with a place of business at 100 College Road West, Princeton, NJ 08540.

5. Counterclaim Plaintiff Alcon Laboratories, Inc. is a Delaware corporation with a place of business at 6201 South Freeway, Fort Worth, TX 76134.

6. On information and belief, Counterclaim Defendant Allergan Sales, LLC is a Delaware corporation with a place of business at 5 Giralda Farms, Madison, NJ 07940.

7. On information and belief, Counterclaim Defendant Allergan, Inc. is a Delaware corporation with a place of business at 5 Giralda Farms, Madison, NJ 07940.

Jurisdiction and Venue

8. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* and the Declaratory Judgment Act. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, 2202.

9. Plaintiffs have consented to personal jurisdiction and venue in this judicial district with respect to these Counterclaims by voluntarily appearing before this Court and filing their Complaint against Defendants here.

Allergan's Wrongful Use of the Patent System

12. The '453 patent is the ninth patent that Allergan has obtained as purportedly covering its drug Combigan®.

13. Combigan® is an ophthalmic drop used for lowering intraocular pressure ("IOP") to treat glaucoma and ocular hypertension that is dosed twice per day ("BID").

14. Combigan is a combination of two ophthalmic drugs, brimonidine and timolol.

15. Brimonidine and timolol each were used for lowering IOP, alone or in combination, long before Allergan put them into a single bottle.

16. Indeed, the '453 patent itself states that "the topical ophthalmic use of brimonidine in combination with timolol" was "available for separate use in the ophthalmic art and have been combined in serial application during the course of treatment of glaucoma." Before Allergan developed Combigan®, it marketed brimonidine under the tradename Alphagan®, which was FDA approved in 1996 with a formulation including brimonidine tartrate (2 mg/mL) as the active ingredient. Allergan recommends that Alphagan® be dosed three times per day ("TID").

17. Timolol was available from a different manufacturer under the tradename Timoptic®. The Timoptic® label indicates that each mL of Timoptic® contains "5 mg of timolol (6.8 mg of timolol maleate)."

18. In the 1990s, doctors routinely prescribed Alphagan® for BID use.

19. In the 1990s, doctors prescribed serial administration of brimonidine and timolol BID to patients for the treatment of glaucoma.

20. In the 1990s, doctors prescribed serial administration of brimonidine and timolol BID to patients for the treatment of ocular hypertension.

21. Allergan's expert in previous cases, Dr. Robert J. Noecker, prescribed serial administration of brimonidine and timolol BID to patients in the 1990s.

22. Serial administration of brimonidine and timolol BID is prior art to the '453 patent.

23. Alphagan® and Timoptic dosed serially BID is prior art to the '453 patent.

24. Brimonidine and timolol dosed serially BID is prior art to the ‘453 patent family.

25. Alphagan® and Timoptic® dosed serially BID is prior art to the ‘453 patent family.

26. Dr. Noecker agreed that serial administration of brimonidine and timolol BID is prior art to the ’453 patent family.

27. In some countries other than the United States, brimonidine is approved for BID dosing.

28. In some countries other than the United States, Alphagan® is approved for BID dosing.

29. Dr. Noecker, admitted that in “some” countries other than the United States, brimonidine is approved for BID dosing.

30. Allergan combined Alphagan® and Timoptic® together into Combigan® to, at least in part, promote patient compliance.

31. At the 2016 bench trial (Case No. 2:15-cv-00347), one of the inventors of the ’453 patent, Ms. Amy Batoosingh, admitted that Allergan was motivated to combine brimonidine with another agent “to make it easier for patients to dose when they need more than one medication.”

32. Though Allergan was not entitled to a patent on Combigan®, it nonetheless sought patent protection in order to block competition from the market.

33. In doing so, Allergan had to contend with the fact that serial administration of Alphagan® and Timoptic® BID was well known in the art.

34. Allergan’s strategy was to obfuscate and misdirect, by maintaining unreasonable positions. For example, Allergan claimed that the closest prior art to Combigan® was not serial

administration of brimonidine and timolol BID, but instead either brimonidine TID alone or serial administration of brimonidine TID and timolol BID.

35. As was common knowledge in the field, though, and as Allergan knew, doctors commonly prescribed Alphagan® BID alone or in serial combination with timolol BID and Alphagan® was approved for BID use in other countries.

36. Despite this knowledge, Allergan asserted that the PTO should consider only that the FDA had approved Alphagan® for TID dosing in the United States rather than how brimonidine was actually used by doctors.

37. Allergan argued that the supposed "unexpected results" of Combigan® as compared to serial administration of brimonidine TID and timolol BID supported patentability.

38. For example, Allergan argued that Combigan® "unexpectedly" showed fewer adverse events (i.e., was safer) than serial administration of brimonidine TID and timolol BID. This was not actually "unexpected," however, as removing a dose of brimonidine exposed the patient to fewer doses of preservatives known to cause such events.

39. Allergan also argued that Combigan® was "unexpectedly" as effective as brimonidine TID alone. This was not actually "unexpected," however, as Combigan® included brimonidine BID and timolol BID, and adding two doses of timolol would have been expected to make up for one less dose of brimonidine.

40. These are clear examples of why "unexpected results" of claimed inventions should be compared to the closest prior art.

41. Had the PTO compared the claims to the closest prior art—serial administration of brimonidine and timolol BID—it would not have granted any of the patents in the '453 patent family.

42. Specifically, during the prosecution of the application that led to the '149 patent (the first patent Allergan filed and received that purportedly covers Combigan®, and parent to the '453 patent asserted here), Allergan submitted results from a 1-month trial comparing Combigan® with serial administration of brimonidine TID/timolol BID and also comparing it with brimonidine TID alone.

43. In its July 27, 2004 amendment, Allergan submitted a declaration stating the results of that study demonstrated that Combigan® resulted in no reported adverse events affecting the central nervous system (including somnolence, depression, dizziness, ataxia, insomnia, and incoordination) while 5% of patients reported such adverse events using serial administration of brimonidine TID/timolol BID (including somnolence at 1.2%) and 5.9% of patients reported such events using brimonidine TID alone.

44. Specifically, Allergan stated, "[t]hat the Combination treatment had no adverse events affecting the central nervous system, while all of the cited methods resulted in a clinically significant percent of patients experiencing adverse events affecting the central nervous system is certainly an unexpected result sufficient to overcome the prima facie case of obviousness that is alleged to exist."

45. These "cited methods" were serial administration of brimonidine TID/timolol BID and brimonidine TID alone.

46. Later on during prosecution of the '149 patent, on August 24, 2005, Allergan stated that "it came to Applicants' attention that another clinical trial had been carried out where some nervous system adverse events were observed."

47. This study, known as "Goni," compared Combigan® to serial administration of brimonidine and timolol BID.

48. Serial administration of brimonidine and timolol BID is the closest prior art to Combigan®.

49. The results of Goni showed that Allergan's previous assertion that Combigan® unexpectedly resulted in no adverse events affecting the central nervous system was incorrect.

50. Yet Allergan continued to argue that the data showed adverse events affecting the central nervous system occurred at a 1.6% rate.

51. Allergan stated that "the frequency of nervous system adverse events [1.6%] was still significantly less than that observed for the three times a day brimonidine, twice a day timolol combination adjunctive therapy [5%]."

52. Allergan did not note that Goni did not address numerous other adverse events affecting the central nervous system, yet Allergan drew a comparison to the rate of occurrence of all of those adverse events.

53. Allergan stated that "the basic conclusion is still valid—that the claimed method reduces nervous system adverse events while maintaining efficacy."

54. Goni actually showed that somnolence occurred at a higher rate in patients treated with Combigan® (1.6%) than patients treated with the serial administration of brimonidine TID and timolol BID (1.2%).

55. Somnolence is an adverse event affecting the central nervous system.

56. This contradicted Allergan's claim that Combigan® resulted in a lesser frequency of adverse events affecting the central nervous system.

57. Allergan understood that its "unexpected results" arguments would not hold if serial administration of brimonidine and timolol BID was compared to the application claims.

58. Allergan argued that serial administration of brimonidine and timolol BID "is not the closest prior art regimen because, as explained above, the person of ordinary skill in the art in this country is likely to follow the FDA recommended thrice a day dosing for brimonidine."

59. Allergan made this argument despite its knowledge that ophthalmologists in the United States were commonly prescribing brimonidine BID alone, and serial administration of brimonidine and timolol BID.

60. Ophthalmologists in the United States are persons of ordinary skill in the art of the '453 patent.

61. Allergan also withheld relevant data on the issue from the PTO.

62. During prior litigation in the Eastern District of Texas regarding related patents (Case No. 2:15-cv-00347), Defendants demonstrated that Allergan's claim language from the '149 patent claim 4 does not cover Combigan®.

63. Specifically, claim language stating that the claimed method is "as effective as the administration of 0.2% w/v brimonidine tartrate monotherapy three times per day" in patients with "glaucoma or ocular hypertension" does not cover Combigan® as demonstrated by the finding that Defendants do not infringe claim 4 of the '149 patent.

64. Allergan's expert, Dr. Mei Sheng Duh, submitted a report that analyzed the data regarding patients with ocular hypertension and patients with glaucoma from Allergan's 12T and 13T studies, which compared treatment with Combigan® against treatment with brimonidine TID and against timolol BID.

65. For the pooled data from both studies, Dr. Duh performed a comparison of IOP lowering effects in the combination group (Combigan®) to the brimonidine TID group based on the mean reduction in IOP.

66. In her comparison, a negative number meant that the combination's IOP lowering effect was numerically lower than that of brimonidine TID.

67. At week 2, hour 9; week 6, hour 9; and month 3, hour 9, the comparison showed a positive number.

68. Thus, at week 2, hour 9; week 6, hour 9; and month 3, hour 9, the comparison showed that Combigan® was not as effective as brimonidine TID.

69. Dr. Duh concluded that "[i]n ocular hypertension patients, the mean IOP reductions from baseline were greater in the brimonidine group than in the combination group at hour 9 at all follow-up visits."

70. Dr. Duh performed a similar comparison in the 12T and 13T studies alone.

71. In the 12T study, the mean IOP reductions from baseline were greater in the brimonidine TID group than in the combination group for ocular hypertension patients at week 6, hour 9 and month 3, hour 9.

72. In the 13T study, the mean IOP reductions from baseline were greater in the brimonidine TID group than in the combination group for ocular hypertension patients at week 2, hour 9.

73. Dr. Duh found that in both studies, brimonidine TID was more effective at lowering intraocular pressure than Combigan® for ocular hypertension patients at multiple timepoints.

74. Thus, Allergan's own data analyzed by its own expert showed that Combigan® is not as effective as brimonidine TID at all timepoints.

75. Allergan did not disclose this information to the PTO during prosecution of the '453 patent.

First Counterclaim
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 9,770,453)

76. Defendants repeat and re-allege the allegations above.

77. Plaintiffs contend that they are the assignee of the ’453 patent. Plaintiffs have sued Defendants in the present action, alleging infringement of the ’453 patent.

78. Defendants are not infringing, and have not infringed, any valid and enforceable claim of the ’453 patent.

79. Thus, an immediate, real and justiciable controversy exists between Plaintiffs, on the one hand, and Defendants, on the other hand, with respect to the alleged infringement of the ’453 patent.

80. Defendants are entitled to a declaratory judgment that they have not and do not infringe any valid and enforceable claim of the ’453 patent.

Second Counterclaim
(Declaratory Judgment of Invalidity of U.S. Patent No. 9,770,453)

81. Defendants repeat and re-allege the allegations above.

82. Plaintiffs contend that they are the assignee of the ’453 patent. Plaintiffs have sued Defendants in the present action, alleging infringement of the ’453 patent.

83. The claims of the ’453 patent are invalid for failing to comply with the requirements of the Patent Laws of the United States, particularly with regard to one or more of the requirements specified in Sections 101, 102, 103, and/or 112 of Title 35 of the United States Code. For example, the claims are invalid for obviousness based on the same reasoning the Federal Circuit employed to invalidate the asserted claims of the ’463 patent.

84. Thus, an immediate, real and justiciable controversy exists between Plaintiffs, on the one hand, and Defendants, on the other hand, with respect to the invalidity of the ’453 patent.

85. Defendants are entitled to a declaratory judgment that one or more claims of the '453 patent are invalid for failing to comply with the requirements of the Patent Laws of the United States.

Relief Requested

WHEREFORE, Defendants respectfully request the following relief:

A. A judgment denying and dismissing Plaintiffs' claims against Defendants with prejudice and denying Plaintiffs' request for damages and injunctive relief;

B. A declaration that Defendants have not infringed, and do not infringe, any valid, enforceable, and properly construed claim of the '453 patent.

C. An order finding that this case is an exceptional case under 35 U.S.C. § 285 and awarding Defendants their reasonable attorneys' fees, expenses, and costs in connection with this action;

D. Any other equitable and legal relief that this Court may deem just and proper.

Jury Demand

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Defendants demand a trial by jury on all issues properly triable to a jury.

Dated: December 19, 2017

Respectfully submitted,

HILL WALLACK LLP

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ATTORNEYS FOR DEFENDANTS / COUNTER PLAINTIFFS

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

On behalf of Defendants/Counterclaim-Plaintiffs Sandoz Inc. and Alcon Laboratories, Inc., I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of other civil actions pending in any Court or of any pending arbitration or administrative proceeding.

Dated: December 19, 2017

Respectfully submitted,

HILL WALLACK LLP

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ATTORNEYS FOR DEFENDANTS / COUNTER PLAINTIFFS

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants/Counterclaim-Plaintiffs Sandoz Inc. and Alcon Laboratories, Inc. hereby certifies that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, inter alia, injunctive relief.

Dated: December 19, 2017

Respectfully submitted,

HILL WALLACK LLP

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ATTORNEYS FOR DEFENDANTS / COUNTER PLAINTIFFS

CERTIFICATE OF SERVICE

This is to certify that a true and correct copy of the foregoing

DEFENDANTS' ANSWER, DEFENSES, AND COUNTERCLAIMS

is to be electronically filed. Notice of this filing will be sent to all parties by operation of the Court's electronic filing system. Parties may access this filing through the Court's system.

December 19, 2017
Date

/s/Christina Saveriano
Christina Saveriano